

MINIMIZING THE IMPACT OF DRUG SHORTAGES ON THE END CONSUMER



In collaboration with

**HDA RESEARCH
FOUNDATION**



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PROJECT PARTICIPANTS

HDA Panel Members

Chris Alverson

Senior Vice President
Supply Chain Management,
McKesson Corporation

Thomas Donahue

Director Category Management,
Value Drug Company

Michael McBride

Vice President, Partner Relations,
Upsher-Smith Laboratories, LLC

Charles Phillips

Vice President Senior Commercial Advisor,
Teva Pharmaceuticals

Heather Zenk

Senior Vice President, Replenishment &
Manufacturer Operations,
AmerisourceBergen Corporation

Erik Little

Vice President Replenishment Operations,
AmerisourceBergen Corporation

Rutgers Team

Anthony Taitt

Assistant Professor of Professional Practice,
Supply Chain Management Department

Musa Tahir

Thomas Abode

Shiwen Qiu

Yingying Hu

HDA and HDA Research Foundation

Perry Fri

Executive Vice President Industry Relations,
Membership and Education, HDA
Chief Operating Officer,
HDA Research Foundation

Justine Freisleben

Vice President Industry Relations, HDA

Rachel Newman

Project Manager, HDA Research Foundation

INTRODUCTION

Background

Every year, hundreds of drugs go on shortage nationally, and in the last decade, the country has seen record-breaking amounts of product shortages. If secondary treatments are not readily available these shortages can result in some patients not being able to obtain the medication they need to survive or maintain a healthy lifestyle. Along with patients, drug shortages impact the pharmaceutical supply chain from the raw material and active pharmaceutical ingredient (API) suppliers, through the manufacturers and distributors, to the pharmacies and dispensers. While most shortages occur due to unknown or difficult to classify causes, the second largest cause is manufacturing problems. These disruptions can occur for a wide variety of reasons. Some potential issues include contamination or quality issues, ingredient availability, regulation concerns and supply chain partner communication.

In collaboration with the Healthcare Distribution Alliance (HDA) Research Foundation, the Rutgers team worked to identify and describe mitigation strategies or best practices to use in managing drug shortages caused by disruptions in manufacturing. HDA established a panel of subject-matter experts (SME). They volunteered their time to participate in interviews, enabling the team to gain a deep understanding of how the SME's organizations manage drug shortages and work to mitigate the impact on the end consumer. Furthermore, the team analyzed data collected by surveying HDA members and affiliate companies.

National Drug Shortages: New Shortages by Year

January 2001 to September 30, 2020

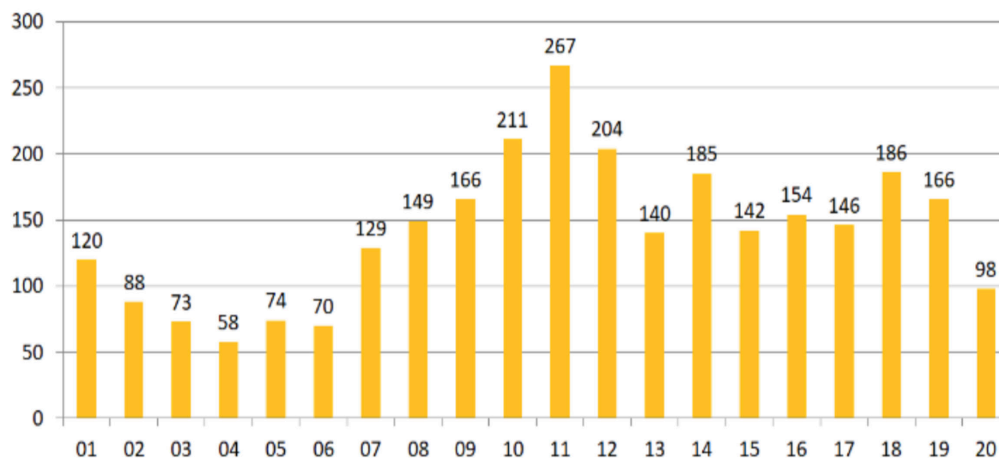


Figure1: Source: American Society of Hospital Pharmacists (ASHP)

Survey

A survey was conducted to understand how various company types (i.e., manufacturer, distributor, pharmacy, healthcare system) dealt with shortages when they occur. The survey consisted of multiple-choice, open-ended, and rating scale questions to better allow respondents to express and elaborate on their opinions. There were 19 total questions listed on the survey, and it was sent out to over 200 organizations. The survey accepted results for two weeks, and at the conclusion, a total of 20 responses were recorded: 55 percent of the responses were from manufacturing companies while 45 percent were from distribution companies. No responses were provided from pharmacies or health systems.

Interviews and Meetings

Throughout the course of the semester the team held seven meetings with HDA representatives and the panel members and conducted four individual interviews with select organizations. The HDA and panel member meetings served to provide the team with information on basic healthcare supply chain functions and discuss common issues faced by all panel members' organizations and understand their perspectives. The four individual interviews included one with a manufacturer and three with distributors of various sizes. The interviews conducted were based on the company's responses to the survey. Interviewees were selected because they expressed unique or conflicting views on the survey questions. These interviews and meetings were critical in developing recommendations on the issue of handling drug shortages and minimizing the impact on the end consumer.

CURRENT SITUATION

Shortages of drugs and medical supplies can be detrimental to patients who need them to overcome illnesses or sustain a healthy life. It is vital for the pharmaceutical supply chain to thoroughly understand the ins and outs of a shortage in order for each organization to optimize its response to ensure that patients receive the life-saving drugs and treatments they require.

The Food and Drug Administration (FDA) defines a drug shortage as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug" (FDA). However, since the pharmaceutical industry is comprised of a very complex supply chain with multiple tiers of suppliers and customers, the definition of a shortage depends on the individual companies involved and their supply chain partners. For example, a given manufacturer can be on contract to produce a certain number of units for a drug.

As long as they meet those requirements, the manufacturer would not consider themselves in a shortage. Issues arise further down the supply chain when consumer demand is greater than what the manufacturer has produced. In this scenario, the distributor and downstream partner's demand is not satisfied, realizing a shortage of the given product.

Through our meetings with the HDA panel, we found that, generally, supply chain partners are confident in their abilities to mitigate the impact of shortages caused by localized disruptions such as natural disasters or logistics delays, etc. The brunt of the downstream issues created by shortages is derived from issues in the manufacturing of drugs. Problems in quality, securing the supply of APIs, spikes in demand, and the regulatory atmosphere are some examples that are unique to manufacturers and often play a role in drug shortages. The issues between supply chain partners often augment these problems.

SURVEY AND RESEARCH RESULTS

Drug shortages harm the entire supply chain, and their causes are often complex and multifactorial. It is very difficult to predict when or if a shortage will occur which adds to the complexity. Some of the factors involved include a lack of consistent communication, government regulation, low visibility in the supply chain and reactionary buying habits. It is crucial for the supply chain to sort out these issues to minimize the effects of the shortage effectively.

Communication and Visibility

Poor communication and insufficient visibility between supply chain partners can lead to disruptions, creating drug shortages. In conducting our research, the Rutgers team found that poor communication and transparency are major issues the supply chain faces in dealing with shortages. Oftentimes, supply chain partners do not receive information from each other about potential issues, so they continue with their regular operations until the issue disrupts the related parts of their operations. This chain of events creates a bullwhip effect that can trigger a frenzy in the supply chain that only worsens matters.

To demonstrate what this means, a common example of a shortage is when distributors do not have time to take appropriate steps to mitigate due to communication issues with their supplier(s). When a manufacturing disruption arises, a manufacturer no longer produces a drug until they solve the issue, which leads to orders going unfulfilled. Oftentimes, distributors do not hear about the disruption until their order does not arrive or they reach out to the manufacturer to check on its status. Upon hearing about the disruption, distributors need to quickly shift to their alternate suppliers to fill their orders, but this poses difficulties. Most

of the time, the other suppliers do not have extra supply to satisfy the sudden increase in purchase orders. In this case, the lack of communication increases the effects of the shortage. Had there been advanced or timely notification of the disruption, other manufacturers may have been able to increase production to try and meet demand. Though this example only demonstrates one scenario of a disruption being exacerbated by the manufacturer’s communication issues, it is essential to note that communication coming from the downstream partners can also lead to manufacturing disruptions.

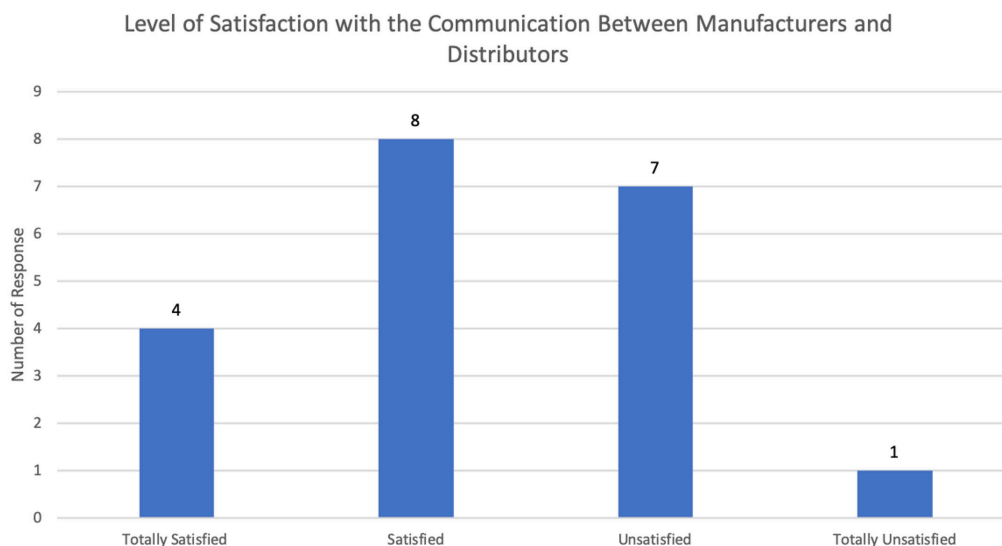


Figure 2: Out of 20 respondents, 12 expressed some level of satisfaction with the communication while 8 expressed some level of dissatisfaction.

As displayed in figure 2, 60 percent of respondents expressed some level of satisfaction with the communication between distributors and manufacturers while 40 percent of respondents expressed some level of dissatisfaction. It is very important to note that although most respondents are overall satisfied with the communication, 10 of the 12 satisfied respondents are manufacturers while 7 of the 8 unsatisfied respondents are distributors. This data indicates a disconnect between what trading partners consider satisfactory or unsatisfactory communication levels, with manufacturers being satisfied with the current standard and distributors being unsatisfied.

The results of our survey also indicate that there is a disconnect between the timeliness of communication between manufacturers and distributors. As shown in figure 3, the Rutgers team asked respondents to share their thoughts on the speed of the communication as it is a critical factor when responding to shortages. Our data show that 9 of the 10 positive, “on-time” or “advanced”, responses were expressed by manufacturers while 8 of the 10 negative, “slow” or “detrimentally slow,” responses were expressed by distributors. Evidently, there is a clear disagreement and much room for improvement in the timeliness of communication between manufacturers and distributors.

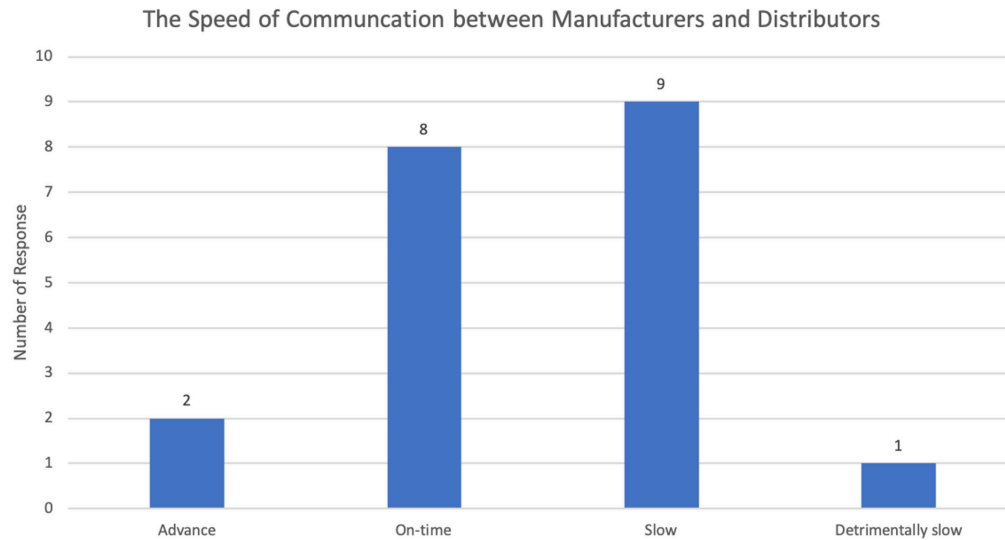


Figure 3: Out of 20 respondents, 10 expressed some level of satisfaction while 10 expressed some level of dissatisfaction.

Another important aspect of communication is the actual information that is being communicated. The team often heard how a lack of transparency between supply chain partners can bring difficulties to each organization's operations. For example, some manufacturers noted that downstream organizations do not like to share information regarding their sales volume, inventory on hand, or information on promotions that may cause a spike in demand. At the same time, distributors shared that the upstream organizations often do not provide enough information on timelines, root causes and lack consistency in their responses. When asked why transparency is essential, all respondents shared the general idea that improved visibility will help their organization be more proactive and effective with their strategies to mitigate the impact of the shortage.

FDA and Regulation

The FDA plays a crucial role in the pharmaceutical industry. It is “the government agency responsible for reviewing, approving and regulating medical products, including pharmaceutical drugs and medical devices” (FDA). When a shortage occurs, the FDA must react quickly to figure out what caused the shortage and determine the correct plan of action to address it. During a shortage, the FDA “works with firms making the drugs that are in shortage to help them ramp up production if they are willing to do so” (FDA). The FDA accelerates the approval process for necessities, such as a new source for raw materials. If U.S. manufacturers are not able to ramp up production and make up for the shortage, the FDA will reach out to manufacturers in other countries and ask to redirect their product into the U.S. for assistance.

The FDA has rules and regulations in place that all pharmaceutical companies must follow. It is continuously creating more guidance documents and regulations in an effort to protect consumers and improve the pharmaceutical supply chain, but these regulations also have the ability to cause disruptions in manufacturing and result in drug shortages. The FDA also has the power to demand that drug production be ceased at any time and without advanced notice. For example, the FDA can exercise a market recall of certain pharmaceutical products. If the FDA deems that certain drugs contain unsafe ingredients, are contaminated, or are mislabeled, they will require a recall which results in manufacturers not being able to continue production. Events like these can then have a domino effect that require distributors and downstream firms to scramble to locate alternative products to be provided to the end consumer. This action increases the pressure on manufacturers because they need to decide if they are going to produce the alternatives and ramp up production in time to make enough of the substitute products to meet demand.

RECOMMENDATIONS

Drug shortages create dire situations for the entire supply chain, and all supply chain partners must work together to minimize the impact of a shortage on the patients. The Rutgers team believes that the organizations that have the most significant influence on the shortage response are the drug manufacturers and distributors. Manufacturers are responsible for creating drugs and need to be able to respond expeditiously to meet the demand. Distributors are responsible for ensuring that healthcare systems and pharmacies have the product their customers need on time and in the right quantities. Both manufacturers and distributors possess essential data that, if shared, can benefit the entire supply chain's response to a shortage. Both organizations can also benefit from improving relationships with each other and adopting strategies for proactively preventing shortages.

Organizational Collaboration

Improving communication is a top priority for all of the research participants (surveyed and interviewed). The data show, there is a significant disconnect between how different organizations perceive their communication abilities and there is much room for improvement in this area. The Rutgers team believes that to reduce the impact of communication shortfalls in the response to shortages, there should be a mutual, collaborative agreement between manufacturers and distributors on a standard set of guidelines for communication when facing shortages. To formulate this agreement, the Rutgers team recommends that manufacturers and distributors, with input from organizations such as the FDA, HDA and the downstream supply chain partners, form cross-functional, cross-organizational teams that enable the

organizations to devise a solution to combat the communication issues jointly. Additionally, the research participants expressed much dissatisfaction with their partner's transparency. Supply chain visibility issues, the Rutgers team believes, are best resolved if manufacturers and distributors work collaboratively to form a set of guidelines to be implemented at the time of a shortage.

Forming cross-organizational teams will enable supply chain partners to develop a shared understanding of both organizations' goals which is one of the most critical enabling conditions for successful teams. This will eliminate the "us versus them" way of thinking and will keep both organizations focused on the main goal of mitigating the impact of a shortage. The Rutgers team also found that organizations may also have internal communication issues which is why we recommend teams be cross-functional. This will ensure that the concerns of all departments in each organization are considered and silos are eliminated. If both organizations are fairly represented and work collaboratively, the team will be better equipped to form effective solutions and strategies. The fragility of shortages cannot be overstated so it is important to note that the purpose of these teams is to create a standard for communication and transparency that should be implemented in times of shortages to minimize the impact of the particular product shortage at hand.



Figure 4: A pictorial representation of a cross-functional, cross-organizational team.

The following are some ideas the Rutgers team recommends for manufacturers and distributors to consider when creating standardized guidelines. These recommendations are based on the results of the survey and the information gained from the meetings and interviews:

- Standardize a more proactive approach;
- Improve relationship and trust with supply chain partners; and,
- Increase supply chain cooperation.

A Proactive Approach

Everyone who is involved in either the buying or selling of pharmaceuticals should take initiative and reach out to provide any necessary information rather than waiting to be asked for it. Reacting to a shortage creates a race against time for all supply chain partners. This can be harmful to the end consumer because some firms are unable to react as effectively as the market needs them to. For this reason, the Rutgers team recommends that firms increase their efforts to actively prepare for worst-case scenarios before they occur. This can include:

Identify Root Cause Proactively

Currently, companies investigate the root cause of shortages once the shortage is identified. Once the root cause is established, the designated departments can begin working on the solution. This method utilizes a reactive approach, which increases the time constraint on the supply chain. If organizations start actively seeking out issues that can be prevented in the manufacturing process, shortages can be prevented from being realized. Companies should adopt the use of technologies and strategies dedicated to monitoring the supply chain, such as, software that gathers inventory levels and retail sales, and Lean and Six Sigma methodology, which emphasizes continuous improvements and operational excellence.

Demand forecasting also plays an essential role in proactively preventing shortages. Manufacturers should consider investing in methods to predict the demand for products more accurately. After all, a shortage is realized when the demand is greater than the supply. Accurate demand forecasting requires a flow of information from all aspects of the healthcare supply chain. Distributors and customers should provide manufacturers with demand predictions on the drugs they expect to receive from that given manufacturer. Through various interviews, the Rutgers team learned that manufacturers communicate with their customers by providing a weekly update. To ensure that communication and information are being shared promptly and accurately, supply chain partners should schedule short weekly meetings in addition to their weekly reports. The constant contact and communication would allow for the most accurate information being shared, ensure that there are no unnecessary bulk or panic buys, and confirm that manufacturers can keep up with the constant change in customer demand.

Manage Inventory Proactively

Companies could incorporate better inventory management before a shortage becomes a relevant issue. One way to do this is by having safety inventory, which would act as a buffer if any upgrades to manufacturing facilities are needed or if there is a transfer of facility ownership. Also, when facing a drug shortage, enough safety inventory would provide a manufacturer additional time to react to the issue at hand and work towards a plan to fix it.

Resource and inventory allocation are also essential techniques to use for inventory management. Manufacturers should be allowed some level of access to view inventory levels that distributors and downstream partners have on hand. This will enable them to examine and recognize if that particular organization is trying to hoard product or if they genuinely need it. Drug allocation is an essential tool for managing shortages; however, the allocation plan's communication is equally important. Manufacturers need to be held accountable for informing their customers of their allocation plan and providing real-time updates regarding the shortage to their customers.

Improving Relationships

More Trust

There needs to be more trust between everyone in the pharmaceutical supply chain. The Rutgers team found that supply chain partners often shift responsibility to each other for shortfalls and could benefit from improving relationships. Improving relationships helps supply chain partners even when shortages are not occurring. During a shortage, supply chain partners should trust each other to make the right decisions that put end consumers first.

More Cooperation

Supply chain partners should also share and accept constructive feedback and suggestions with each other as the supply chain is only as strong as its weakest link. Larger organizations in the pharmaceutical supply chain should offer guidance programs to their smaller partners who could benefit from their expertise. Smaller organizations are encouraged to participate in these programs as it is only to their benefit.

Internal Cooperation

Most, if not all, tiers of the pharmaceutical supply chain need to develop standardized procedures that will enable more efficient internal processes, enhance the interactions between each other, and maximize the response times when faced with a drug shortage. Additionally, these companies should improve their database maintenance to improve real-time information sharing and tracking. Internally, roles and responsibilities must be made clear for each different department. Distinct roles within the manufacturing process will ensure greater efficiency and internal cooperation and ultimately benefit the supply chain process.

External Cooperation

Companies should work to improve external cooperation by maintaining communication with the many external groups affected by drug shortages, such as patients, health professionals, federal partners, and international groups. The industry should take the initiative in engaging in more dialogue with the FDA to work on a long-term solution to shortages. The FDA also can take the initiative to work towards solutions to address shortages and potentially provide incentives for manufacturers. For example, they can create excellence standards for each manufacturer to follow, such as always having an agreed-upon amount of raw materials, which will essentially prove the reliability of each manufacturer's supply chain. If each manufacturer follows the guidelines, they could be eligible for some type of reward that the FDA deems appropriate, whether it be an economic incentive, public recognition, etc. Implementation of this or a similar concept would reduce the probability of a shortage because each manufacturer would have incentives to stop the problem before it even begins.

CONCLUSION

Product shortages are an unfortunate reality of the pharmaceutical industry. Due to their complexities, it is unlikely that they will be resolved entirely with the pharmaceutical industry's current technologies and environment. In conducting this research, the Rutgers team hopes that these insights will help the industry recognize the areas of concern pointed out and implement new strategies to mitigate the impact of drug shortages. The areas of concern the Rutgers team places emphasis on are supply chain communication, visibility and regulation. To improve these areas, the Rutgers team recommends supply chain partners, primarily manufacturers and distributors, collaborate with each other to form a standard set of guidelines to be implemented when a shortage is realized. Guidelines should contain strategies for being more proactive, improving relationships, and influencing long-term change in the regulatory environment to benefit companies who exhibit operational excellence. The end goal is to strengthen all supply chain participants' abilities to respond when a shortage is realized so that the shortage has minimal to no impact at all on the end consumer.

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HDA Research Foundation
901 North Glebe Road, Suite 1000
Arlington, VA 22203

(703) 787-0000
(703) 812-5282 (Fax)

www.hda.org/foundation